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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/816,011	03/11/1997	MARK H. PAUSCH	34.421-C2	6532

22852 7590 04/09/2002

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EXAMINER

PAK, MICHAEL D

ART UNIT PAPER NUMBER

1646

DATE MAILED: 04/09/2002

35

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/816,011

Applicant(s)

Pausch et al.

Examiner

Michael Pak

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED-STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 28, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 36-39 is/are pending in the application.
- 4a) Of the above, claim(s) 1-21, 23, 25, 26, 28, 31, 32, and 36-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22, 24, 27, 29, 30, and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1.5
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. Preliminary amendment filed 28 January 2002 (Paper No. 34) has been entered.
2. Applicant's election with traverse of Group VI, C. Elegans CORK nucleic acid of claims 22, 24, 27, 29-30, and 33, in Paper No. 34 is acknowledged. The traversal is on the ground(s) that the examination of the non-elected claims would not place a serious additional burden on the examiner. This is not found persuasive because each protein is structurally different and each requires a separate search in the sequence databases.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 24 is withdrawn in part from consideration as being directed to a non-elected invention for claim limitation drawn to SEQ ID NO:1 which is the Drosophila Dm ORF1.

Sequence Rules 37 CFR 1.821-1.825

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825. The Paper copy of the sequence listing does not appear to agree with the submitted CRF especially for SEQ ID NO:36.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 22, 24, 27, 29-30, and 33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are directed to a polynucleotide encoding C. Elegans CORK two pore potassium channel and vectors comprising the polynucleotide, and cells comprising the vectors. The specification on page 33 disclose the asserted utility of using the two pore potassium channel as targets for therapeutics in humans. However, there is no nexus between the two pore potassium channel and the therapeutics for humans. The specification as filed does not disclose or provide evidence that points to a property of the claimed two pore potassium channel such that another non-asserted utility would be well established.. The polypeptide lacks substantial utility because further research to identify or reasonably confirm a "real world" context of use is required. Thus, the asserted utility lacks substantial and specific utility because further research to identify or reasonably confirm a "real world" context of use is required. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that "Congress intended that no patents be granted on an chemical compound whose sole "utility" consists of its potential role as an object of use-testing ... a patent is not a hunting license." *Brenner* further states that "It is not a reward for the search , but compensation for its successful conclusion." Any utility of the nucleic acid

encoding the protein or other specific asserted utility is directly dependent on the function of the protein. A circular assertion of utility is created where the utility of the protein is needed to break out the circular assertion of utility. The claimed polypeptides do not substantial utility because the skilled artisan would need to prepare, isolate, and analyze the protein in order to determine its functional nexus with human therapeutics. Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself would be required before it could be used. The disclosed use for the nucleic acid molecule of the claimed invention is generally applicable to any nucleic acid and therefore is not particular to the nucleic acid sequence claimed. The claims directed to vectors and host cells do not have utility because the nucleic acid without utility is needed to practice the inventions.

Claims 22, 24, 27, 29-30, and 33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 22, 24, 27, 29-30, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recite "capable of encoding a protein designated CORK" which is ambiguous because it not clear what is the metes and bounds of the claimed nucleotide. The claims recited not structural limitations and the molecule is only defined by functional name CORK. Furthermore, a nucleic acid sequence which is capable of encoding a protein is not limited to the encoding protein.

Claim 24 recite "nucleotide sequence of SEQ ID NO: ... 36" which is confusing because SEQ ID NO:36 is an amino acid sequence in the CRF search.

Claim 24 is ambiguous because of claim limitation drawn to a non-elected SEQ ID NO:1.

Claim 24 recite the term "hybridizes" which relative term whose metes and bounds are not clear.

Claim 24 recite "functional derivative" which is ambiguous because it is not clear what is the metes and bounds of the term which is not limited by structure or function.

Claim 27 is confusing because it is dependent on non-elected claim 16. Claim 30 is dependent on claim 27.

Claim 27 is ambiguous because it is not clear what is the metes and bounds of the terms which does not claim the structure of the compound.

Claim 29 is ambiguous because expression vectors are not capable of expressing potassium channels in the cell membrane.

~~Claim 33 is confusing because it is dependent on non-elected claim 32 and because claim 32 is drawn to a method not a nucleic acid.~~

8. Claims 22, 24, 27, 29-30, and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This a written description rejection.

Claims 22 encompass an isolated nucleic acid encoding variants and fragments of proteins because the claim is only limited by the functional name CORK. Claims 24 encompass an isolated nucleic acid encoding variants and fragments of proteins because the claim is drawn to "hybridizes" limitation and "functional derivative" limitation. Claim 29 is dependent on claim 24. Claim 27 encompass expression vector comprising nucleic acid molecules encoding variants and fragments because the claims do not contain structural limitations and are only limited by the functional languages. Claim 27 further encompass nucleic acid variants drawn generically to all animals and invertebrates. Claim 30 is dependent on claim 27. Claim 33 appears to be only limited by SEQ ID NO: but it is not clear from the claim construction. However, the essential feature of the invention is the nucleic acid molecule which encodes a CORK two pore potassium channel of SEQ ID NO:36, and one of skilled in the art cannot envision the full genus of molecules of the claimed variant nucleic acid molecules. The claims encompass nucleic acid molecule encoding variants whose structure is not known or nucleic acid molecules encoding other variant proteins with different function from CORK taught in the specification. Claimed

nucleic acid encoding protein variants encompass a large genus of proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

9. No claims are allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael D. Pak
Michael Pak
Primary Patent Examiner
Art Unit 1646
5 April 2002